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SERIAL NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET NO.
024,111	03/26/79	Yasuhide Tachi et al.	A13132P1

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EXAMINER	
E. Roberts	
ART UNIT	PAPER NUMBER
125	14

DATE MAILED:

MAILED

This is a communication from the examiner in charge of your application.

COMMISSIONER OF PATENTS AND TRADEMARKS

JUL 3 1980

☐ This application has been examined.

☒ Responsive to communication filed on _____

GROUP 120
☐ This action is final.

A shortened statutory period for response to this action is set to expire 3 month(s), _____ days from the date of this letter.
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

- ☒ Notice of References Cited, Form PTO-892.
- ☐ Notice of Informal Patent Drawing, PTO-948.
- ☐ Notice of Informal Patent Application, Form PTO-152.
- ☐ _____

Part II SUMMARY OF ACTION

- ☒ Claims 1 15 are pending in the application.
Of the above, claims _____ are withdrawn from consideration.
- ☐ Claims _____ have been cancelled.
- ☐ Claims _____ are allowed.
- ☒ Claims 1 15 are rejected.
- ☐ Claims _____ are objected to.
- ☐ Claims _____ are subject to restriction or election requirement.
- ☐ The formal drawings filed on _____ are acceptable.
- ☐ The drawing correction request filed on _____ has been ☐ approved. ☐ disapproved.
- ☐ Acknowledgment is made of the claim for priority under 35 U.S.C. 119. The certified copy has
☐ been received. ☐ not been received. ☐ been filed in parent application, serial no. _____
filed on _____.
- ☐ Since this application appears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.
- ☐ Other

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The finality of the rejection dated March 10, 1980 is hereby removed in view of the newly cited reference. It is the Examiner's position that the reference is necessary in order that a proper resolution of the issue of patentability be obtained.

Claim I is the sole claim in the case.

Claim 1 is rejected under 35 U.S.C. 103 as being obvious from the disclosure of Ercoli et al. in combination with Elks et al. (2) , newly cited. The primary reference discloses the 17,21-d¹, ester of hydrocortisone at column 4, lines 4 and 9. The secondary reference discloses the fact that the anti-inflammatory activity of 17 α , 21-dihydroxy hydrocortisone derivative could be enhanced, with little risk of disturbance of the mineral balance and other systemic activity should the compound be absorbed, by preparing the 17 -mono and 17,21-diesters of the parent compound. The reference teaches the method of preparing said esters and shows the procedures of introducing an ester function at C-21 which is the same or different from the function at C-17. In view of the teaching of the secondary reference, it is ^{the} Examiner's position that the 17 -butyrate-21-propionate d¹ ester derivative of

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Ercoli et al's compound would be obvious to one skilled in the art; especially in view of the fact that Example 29 specifically shows the combination.

Applicants arguments as well as the declarations placed of record have been carefully considered but are not deemed to be of such a magnitude as to be persuasive of patentability. The affidavits placed of record to establish patentability have no probative value since they fail to overcome the teachings of the secondary reference. It appears to the Examiner that the advantage relied upon for patentability by applicants would be inherently present in the reference since Example 29 shows the same di-ester combination. It would be interesting to find out what observations could be made when comparing the biological properties of beta methasone 17-valerate-21-acetate against the compound in Example 29. In all probability the therapeutic effectiveness of the di-acylate in Example 29 would be about 10 times greater than that of the 17-valerate-21-acetate of the beta methasone. In view of the extensive teachings of the prior art, the specifically claimed compound is deemed a modification of a well known anti-inflammatory compound that would be obvious to those skilled in the field of steroids.

This application should be prepared
for Final Rejection. S.S.P. (3 months)

Elbert L. Roberts
Elbert L. Roberts
Primary Examiner
Art Unit 125

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06/26/80